DETAILED ACTION

Applicant filed a response to the Non-Final Action of July 13, 2007 on January 10, 2008. Claims 1-5, 9-27 are cancelled.

Claims 6-8 are under consideration.

Withdrawn Rejection

35 USC § 112, 1st parag., Enablement

Applicant's arguments, see pages 4-7, filed January 10, 2008, with respect to the rejection of claims 6-8 have been fully considered and are persuasive. Applicant indicates that the instant claims are directed to a method of engrafting mesenchymal stem cells. Passages from Bianco cited in the Office Action, July 13, 2007, page 7, are directed to generation of an entire organ or system, and do not address engraftment (Applicant's emphasis, Applicant's response, page 6). The rejection of claims 6-8 has been withdrawn.

New Rejection

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 6-8 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Srour et al., US Patent 5,672,346, patented September 30, 1997 in view of Prockop, 1997, Biomedicine & Pharmacotherapy 51: 407-408, Srour et al., 1992, Blood, 79: 1404-1412.

Srour et al. teach a method of obtaining persistent maintenance of grafted human hematopoietic cells in a mammal. The method includes the step of grafting the mammal in utero with a cellular composition. Grafted mammals have been shown to be highly persistent in maintaining hematopoietic characteristics of the graft, for example well beyond grafting and birth (Srour et al., col. 3, lines 21-39). Srour et al. teach bone marrow (BM) graft cells (CD34+, HLA-DR-) were injected into several 42-48 day old sheep fetuses intraperitoneally through a 22-gage needle (Srour et al., col. 29, under “In utero transplantation”).

While Srour et al. teach hematopoietic stem cells, they do not teach mesenchymal stem cells.

Prockop teaches that when donor mesenchymal stem cells from normal mice are infused in large amounts into young mice that are feeble because they express a mutated collagen gene, the normal donor cells replace up to 30% of cells in bone, cartilage, and brain of the recipient mice. The results are the basis of a clinical trial now in progress for therapy of bone defects seen in children with severe osteogenesis imperfecta because of mutations in the genes for type I collagen. The treatment converts a severe bone defect to a mild one (Prockop, page 407, under “Marrow stem cells for non-hematopoietic tissues"). Prockop also teaches that engraftment of whole

marrow can be obtained in mice or dogs without the need for marrow ablation if large numbers of cells are infused or if they are infused at regularly spaced intervals (Prockop, page 408).

Both Srour et al. and Prockop teach that stem cells can be transplanted into animals and it would have been obvious for an artisan to substitute the hematopoietic cells taught by Srour et al. with the mesenchymal stem cells taught by Prockop in order to achieve the predictable result of arriving at an animal that comprises mesenchymal stem cells. It is also noted that an artisan would have used the method of introducing cells to fetuses, as taught by Srour et al., because the fetuses would take up the mesenchymal cells taught by Prockop and an artisan would arrive at baby animals that were treated from the day when they were born.

With regard to using human mesenchymal stem cells, an artisan would have used human mesenchymal stem cells in heterologous animals (e.g. sheep) to test the feasibility of transplantation before proceeding in humans. Srour et al. teach that xenogeneic transplants can be performed when the fetus is preimmune (i.e. in its first trimester) (Srour et al., page 1404, 1st col., 1st parag.).

As such, the claims are obvious.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-

272-2911. The examiner can normally be reached Monday through Thursday and alternate Fridays from 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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/Joanne Hama/
Art Unit 1632